NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PIRAMAL HEALTHCARE UK LIMITED, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORP. and NOVARTIS AG, Defendants.	**Civil Action No. 19-12651 (SRC)** **OPINION** **CONFIDENTIAL INFORMATION REDACTED PURSUANT TO L. PAT R. 2.2**

CHESLER, District Judge

This matter comes before the Court upon the motion filed by Defendants Novartis Pharmaceuticals Corp. and Novartis AG (collectively, "Defendants" or "Novartis") to dismiss the First Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(1) for lack of subject matter jurisdiction. Defendants also request, in the alternative, that the Court stay this litigation. Plaintiff Piramal Healthcare UK Limited ("Plaintiff" or "Piramal") has opposed the motion. The Court has considered the papers filed by the parties. For the reasons that follow, Defendants' motion will be denied.

I. BACKGROUND

In this this Hatch-Waxman action, Plaintiff Piramal seeks a declaratory judgment of non-infringement as to U.S. Patent No. 9,283,209 ("the '209 Patent"), entitled "Oral Formulations of Deferasirox" and issued on March 15, 2016. Defendant Novartis AG is the owner of record with the United States Patent and Trademark Office ("USPTO") of the '209 Patent. Defendant

Novartis Pharmaceuticals Corp. is the holder of a New Drug Application ("NDA") for Jadenu®, a drug for the treatment of iron overload in patients.[1]

On March 30, 2015, the Food and Drug Administration ("FDA") approved Jadenu for sale in three strengths: 90 mg, 180 mg, and 360 mg. Novartis owns two patents listed in the Orange Book as covering Jadenu: the '209 Patent as well as U.S. Patent No. 6,465,504 ("the '504 Patent"). The '504 Patent expired on April 5, 2019, but the patent-in-suit, the '209 Patent, is not due to expire until November 21, 2034. Novartis submitted the '209 Patent for listing in the Orange Book on April 11, 2016.

On December 31, 2018, Piramal filed an Abbreviated New Drug Application ("ANDA") with the FDA as to each of the three dosage strengths of deferasirox, seeking the FDA's approval to market Piramal's generic equivalent versions of Jadenu. Piramal's ANDA contains a Paragraph III certification as to the '504 Patent, certifying that Piramal will wait until the '504 Patent expires to begin marketing its products. It also contains a Paragraph IV certification as to the '209 Patent, certifying that Piramal's deferasirox products will not infringe the '209 Patent.

After filing its ANDA, Piramal sent notice to Novartis of the Paragraph IV certification concerning the '209 Patent. Pursuant to the Hatch-Waxman Act, the notice gave rise to Novartis' right to sue Piramal for patent infringement. Novartis, however, chose not to sue Piramal within

[1] The Court will hereinafter refer to the branded drug at issue simply as "Jadenu," eliminating the symbol denoting its trademark registration.

the 45-day period provided by statute. On or about May 13, 2009, [redacted].

It is undisputed that Piramal was not the first applicant to file an ANDA referencing Jadenu. Indeed, as Novartis points out, various other pharmaceutical companies had previously submitted ANDAs concerning generic forms of all strengths of Jadenu, including a company known as Actavis Elizabeth, LLC ("Actavis"). (Actavis is not a party to this litigation, but the Court notes its status as an earlier ANDA filer in light of this fact's significance to Novartis' motion, as the Court will discuss below.) It is further undisputed that Novartis has not sought to enforce its rights to the '209 Patent as against Piramal or any other generic pharmaceutical company.

It was Piramal that initiated this civil action for a declaration that its deferasirox ANDA products do not infringe the '209 Patent. The Complaint, filed May 17, 2019, alleged that Piramal brought the action because "Novartis has not sued Piramal for patent infringement and has not provided Piramal with any assurances it will not sue Piramal for infringement of the '209 patent." (Compl., ¶ 31.) On June 28, 2019, Novartis moved to dismiss the Complaint, arguing primarily that the controversy had become moot by virtue of a covenant not to sue, executed by Novartis and delivered to Piramal on June 12, 2019. In the covenant, Novartis promised "not to assert any claim of infringement of, or otherwise enforce or attempt to enforce, the '209 Patent against Piramal based on the manufacture, use, sale, offer for sale, or importation into the United

States of the Piramal ANDA Products . . ..” (Cook Decl., June 28, 2019, Ex. A.) Novartis urged Piramal to discontinue the litigation, but Piramal instead filed the Amended Complaint, which is the subject of the instant motion.

As pled in the Amended Complaint, the litigation no longer concerns the 90 mg and 360 mg deferasirox products. However, Piramal now alleges that its “180 mg strength deferasirox tablets . . . will be blocked from receiving final approval [from the FDA] and prevented from actually entering the market until the end of the first-filer’s exclusivity based on the ’209 Patent,” i.e., until the expiration of a marketing exclusivity period afforded by statute to the first ANDA filer for the drug, or until the exclusivity is “otherwise resolved.” (Am. Compl., ¶ 49.) As a basis for the ongoing controversy between Piramal and Novartis, notwithstanding the covenant not to sue, the Amended Complaint invokes the Hatch-Waxman provision concerning forfeiture of such first-filer exclusivity. See 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb). Under that provision, the Amended Complaint asserts, a judgment of non-infringement of the unexpired patent covering the 180 mg deferasirox, i.e., the ’209 Patent, is necessary to trigger forfeiture of the first-filer’s exclusivity.

Piramal alleges that, according to the FDA, another ANDA applicant holds the first-filer exclusivity to market the 180 mg deferasirox tablets. As a result, the Amended Complaint alleges, Piramal’s ANDA cannot be approved by the FDA unless and until the exclusivity block is cleared through a judgment of non-infringement. It further alleges that Piramal’s injury, the preclusion of Piramal’s 180 mg deferasirox product from the market, stems from the actions of Novartis. The Amended Complaint avers that because Novartis has listed the ’209 Patent in the Orange Book yet has avoided subjecting the patent to an adverse judgment, the first-filer exclusivity remains in place. Piramal alleges that “absent a judgment from this Court declaring

that Piramal's proposed generic 180 mg deferasirox tablets do not infringe the '209 Patent, Piramal will be unable to sell its generic 180 mg deferasirox tablets indefinitely, thereby injuring Piramal by depriving it of sales revenue that it could earn for that period of time." (Id., ¶ 51.)

II. DISCUSSION

In this motion to dismiss for lack of jurisdiction, Defendants argue that Piramal lacks standing to bring this action for a declaration of non-infringement for two reasons: (1) Piramal has failed to allege any injury, as no exclusivity period for the 180 mg deferasirox exists and Novartis has promised it will not sue for infringement of the '209 Patent and (2) even assuming the exclusivity exists, i.e., has not been forfeited by another ANDA filer, Piramal fails to allege a concrete loss because any profits from the product at issue will not exist, Novartis contends, by the time Piramal's ANDA is approved. In other words, Novartis maintains that Piramal lacks standing because it has not sustained any injury-in-fact. "Standing is a threshold jurisdictional requirement, derived from the 'case or controversy' language of Article III of the Constitution." Public Interest Research Group v. Magnesium Elektron, 123 F.3d 111, 117 (3d Cir. 1997) (citing Valley Forge Christian College v. Americans United for Separation of Church and State, 454 U.S. 464, 471-73 (1982)). Because standing is a jurisdictional matter, Federal Rule of Civil Procedure 12(b)(1) governs the instant motion to dismiss. Ballentine v. United States, 486 F.3d 806, 810 (3d Cir. 2007).

Under Rule 12(b)(1), subject matter jurisdiction may be challenged on either the face of the pleadings or on the facts underlying the existence of jurisdiction. Mortensen v. First Fed. Sav. & Loan Assoc., 549 F.2d 884, 891 (3d Cir. 1977) (drawing a distinction between a facial

attack and a factual attack on subject matter jurisdiction under Rule 12(b)(1)). A facial challenge asserts that a claim, on its face, is "insufficient to invoke the subject-matter jurisdiction of the court because, for example, it does not present a question of federal law," whereas a factual challenge maintains "that there is no subject matter jurisdiction because the facts of the case . . . do not support the asserted jurisdiction." Constitution Party of Pa. v. Aichele, 757 F.3d 347, 358 (3d Cir. 2012). "In evaluating a Rule 12(b)(1) motion, a court must first determine whether the movant presents a facial or factual attack," as the court's review of the motion will differ depending on the kind of challenge. In re Schering Plough Corp. Intron/Temodar Consumer Class Action, 678 F.3d 235, 243 (3d Cir. 2012) (citing Mortensen, 549 F.2d at 891); see also Aichele, 757 F.3d at 357 (holding same).

In the motion before the Court, Novartis challenges jurisdiction based on information indicating, it contends, that there is an error in FDA records showing that there is an exclusivity period for the 180 mg deferasirox tablets. Defendants' motion clearly presents a factual attack on subject matter jurisdiction by contesting the basis of Piramal's allegation that approval of its ANDA is precluded so long as the exclusivity period exists. In considering a factual Rule 12(b)(1) motion, the Court "can look beyond the pleadings to decide factual matters related to jurisdiction." Cestonaro v. United States, 211 F.3d 749, 752 (3d Cir. 2002). The Third Circuit has held that, on a factual attack, "no presumption of truthfulness attaches to the allegations of the plaintiff." CNA v. United States, 535 F.3d 132, 139 (3d Cir. 2008).

As noted above, Defendants base their motion to dismiss on Plaintiff's alleged lack of standing for failure to demonstrate it has sustained injury-in-fact. The burden is on a plaintiff to demonstrate that it has standing. Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992). To

establish standing, a plaintiff must show that (1) it "suffered an injury in fact, an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural, or hypothetical;" (2) there is a "causal connection between the injury and the conduct complained of - the injury has to be fairly ... traceable to the challenged action of the defendant, and not ... the result of the independent action of some third party not before the court;" and (3) "that the injury will be redressed by a favorable decision." Id. at 560-561.

Given that Plaintiff's alleged injury stems from the operation of certain provisions of the Hatch-Waxman Act, the Court will briefly set forth the pertinent provisions. The Hatch-Waxman Act grants the first applicant to file a "substantially complete" ANDA containing a Paragraph IV certification the exclusive right to sell its product for 180 days alongside the brand-name product. 21 U.S.C. § 355(j)(5)(B)(iv). In other words, for the 180-day exclusivity period, the first-filer generic is the only competitor of the brand-name manufacturer (NDA holder) in the market. Under the statute, the 180-day exclusivity period does not begin to run until the first ANDA filer puts its product on the market. The statute further provides that no subsequent ANDA filer can receive final approval for its generic drug product until the first-filer's exclusivity period has run its course or been forfeited.[2] Id.

The 180-day exclusivity may be forfeited in a number of ways. 21 U.S.C. § 355(j)(5)(D)(i)(I)-(VI (setting forth various forfeiture events). In relevant part, the statute provides that forfeiture occurs when: (1) the first ANDA filer "amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification

[2] Only the first ANDA filer for a drug may obtain the 180-day exclusivity period; subsequent applicants are not eligible, even in the event a first filer forfeits. 21 U.S.C. § 355(j)(5)(D)(ii)-(iii).

qualifying the applicant for the 180-day exclusivity period;" 21 U.S.C. § 355(j)(5)(D)(i)(III), or (2) the first ANDA filer fails to market the generic drug within a certain period of time following a court's entry of final decision that the patent is invalid or not infringed. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb). The latter forfeiture event is known as the "failure-to-market forfeiture provision." Summarizing the two requirements for failure-to-market forfeiture, the Federal Circuit has stated: "a court must have entered a final decision of non-infringement that is no longer appealable (certiorari aside), and the second (or later) filer must have received tentative approval. The first filer forfeits its exclusivity if it has not entered [the market] 75 days after those two requirements are satisfied." Apotex v. Daiichi Sankyo, Inc., 781 F.3d 1356, 1369 (Fed. Cir. 2015).

Where the first ANDA filer has obtained the 180-day exclusivity, a subsequent filer may seek to trigger the failure-to-market forfeiture provision by filing a declaratory judgment action to obtain patent certainty. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA); see also Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd., 527 F.3d 1278, 1284 (Fed. Cir. 2008) ("subsequent Paragraph IV ANDA filers can trigger the first Paragraph IV ANDA filer's 180-day exclusivity period via the court-judgment trigger."). The Federal Circuit has explained the purpose of providing this statutory mechanism for relief to subsequent ANDA filers, as follows:

> Since the FDA cannot approve subsequent Paragraph IV ANDAs until the first Paragraph IV ANDA filer's 180-day exclusivity period expires, the date on which the exclusivity period is triggered is critical to NDA holders and subsequent Paragraph IV ANDA filers. On the one hand, subsequent Paragraph IV ANDA filers have a strong incentive to generate a triggering event allowing the FDA to approve their subsequent Paragraph IV ANDAs 181 days after the triggering event. On the other hand, NDA holders have a strong incentive to prevent a triggering event, because subsequent Paragraph IV ANDAs cannot be approved until the exclusivity

> period expires . . . NDA holders have a strong incentive to avoid litigation that would trigger the first Paragraph IV filer's exclusivity period and allow the FDA to approve subsequent Paragraph IV ANDAs 181 days after the triggering event.

Id. The 180-day exclusivity, combined with the branded drug manufacturer's avoidance of litigation concerning the validity or infringement of an Orange-Book-listed patent, delays FDA approval of a subsequent ANDA and thus delays a subsequent filer's entry into the market. Id. at 1285. This constitutes the "blocking injury" of which Plaintiff Piramal complains in its Amended Complaint, and the Federal Circuit has clearly held that such an injury is a sufficient injury-in-fact to satisfy an ANDA filer's standing to sue the NDA holder. Id. at 1292. In Caraco, the Federal Circuit discussed the nature of the injury, holding as follows:

> [W]here the first Paragraph IV ANDA filer has failed to trigger its own 180-day exclusivity period, the NDA holder's listing of Orange-Book patents delays a subsequent Paragraph IV ANDA filer from entering the marketplace indefinitely. Moreover, this delay occurs even if the drug described in the subsequent Paragraph IV ANDA does not infringe the Orange-Book-listed patents . . . Under these circumstances, the [NDA holder's] listing of the [subject] patent (the patent-in-suit) in the Orange-Book creates an independent barrier to the drug market that deprives Caraco [the subsequent ANDA filer] of an economic opportunity to compete.

Id. at 1292-93; see also Teva Pharms. USA, Inc. v. Eisai Co., 620 F.3d 1341, 1347 (Fed. Cir. 2010), vacated on procedural grounds, 426 F. App'x 904 (Fed. Cir. 2011) ("*Caraco* holds that the exclusion of non-infringing generic drugs from the market can be a judicially cognizable injury-in-fact.").

Moreover, the Federal Circuit has consistently held that a declaratory judgment action brought by a subsequent Paragraph IV ANDA filer to trigger a first-filer's 180-day exclusivity presents an actual controversy under Article III where approval of its ANDA is blocked. Caraco,

527 F.3d at 1293-94; see also Eisai, 620 F.3d at 1347-48 (holding that because the "independent barrier" to FDA approval and marketplace entry posed by the Orange Book listing of a patent cannot be overcome without a court judgment, a declaratory judgment action presents an actual controversy). Indeed, in Caraco, the Federal Circuit reviewed all three elements of Article III standing as they apply to a subsequent Paragraph IV ANDA filer's declaratory judgment action against the NDA holder to trigger the first-filer's exclusivity period. Caraco, 527 F.3d at 1291-94. It held that the blocking injury, that is, the indefinite delay of a subsequent ANDA filer's entry into the marketplace, is traceable to the NDA holder's listing of patents in the Orange Book, thus satisfying the second requirement for Article III standing. Id. at 1293-94; cf. Janssen Pharmaceutica, N.v. v. Apotex, Inc., 540 F.3d 1353, 1361 (Fed. Cir. 2008) (distinguishing between exclusion from the market due to the 180-day exclusivity period and exclusion due to an NDA holder's assertion that its NDA covers a valid listed patent, and holding that the former "is not a cognizable Article III controversy but a result envisioned by the Hatch-Waxman Act."). The Caraco court also held that the injury is redressable though a declaratory judgment that the patent at issue is not infringed, as a favorable judgment would eliminate the impediment to FDA approval of the subsequent ANDA. Id. at 1294. Finally, and of significance to the case at bar, the Federal Circuit has squarely rejected the argument that a branded manufacturer's covenant not to sue a subsequent ANDA filer for patent infringement moots the controversy in circumstances where a 180-day exclusivity exists, reasoning that a judgment of invalidity or non-infringement with respect to the relevant Orange Book-listed patents is required to redress the blocking injury. Daiichi, 781 F.3d at 1362-64; Eisai, 620 F.3d at 1345; Caraco, 527 F.3d at 1296-97.

Novartis argues that Piramal does not and cannot demonstrate that such a first-filer impediment exists with regard to approval of Piramal's ANDA for the 180 mg strength of its generic version of Jadenu. In other words, according to Novartis, there is no factual basis for the injury Piramal alleges in its Amended Complaint. Thus, Novartis maintains, the covenant given by Novartis not to sue Piramal for infringement of the '209 Patent indeed moots this declaratory judgment action.

In light of the governing law, the key question before the Court on Novartis' motion to dismiss for lack of standing is as follows: Has Piramal alleged and adequately demonstrated, at this stage of the litigation, that it has sustained a blocking injury as to its ANDA for 180 mg deferasirox tablets, based on the Orange Book-listed '209 Patent and the existence of another Paragraph IV ANDA filer's 180-day exclusivity for the drug? The answer is yes.

Piramal has come forward with substantial evidence indicating that another ANDA filer (whose identity remains confidential in accordance with FDA policy) retains the right to the 180-day commercial exclusivity as to the generic 180 mg deferasirox product, which precludes Piramal from obtaining final FDA approval of its product. The first piece of evidence consists of

[redacted]

[redacted]. (See Hernandez Decl., ¶ 7.) In addition, the FDA's Paragraph IV Certification Database, available on its website, shows that on July 16, 2019 updated information was posted as to the 180-day exclusivity status for all three strengths of deferasirox. The FDA's updated database states that while the 180-day exclusivity has been extinguished as to the 90 mg and 360 mg products, the 180 mg product remains eligible for 180-day exclusivity, based on an ANDA submitted on April 21, 2016. It further shows that the expiration date of the last qualifying patent on the 180 mg deferasirox is November 21, 2034 (the date the '209 Patent expires), whereas the last qualifying patent on the other strengths expired on April 5, 2019 (the date the '504 Patent expired). Piramal also points to another FDA source, which publishes the date on which a substantially complete ANDA containing a Paragraph IV certification is submitted. According to Piramal, the source shows a submission date of October 19, 2015 for ANDAs referencing the 90 mg and 360 mg strengths of Jadenu but April 21, 2016 as the submission date for a substantially complete ANDA for the 180 mg deferasirox. The latter submission, of April 21, 2016, post-dates the listing of the '209 Patent in the Orange Book, emphasizing, Piramal argues, that the 180-day exclusivity for 180 mg deferasirox attached from both the (then-unexpired) '504 Patent and the '209 Patent. Based on the foregoing, Piramal maintains, its ANDA for 180 mg deferasirox is subject to a barrier to approval, which will remain in place until the first ANDA filer forfeits the exclusivity or the '209 Patent expires.

Novartis contends that the information provided by the FDA must be wrong, because it is at odds with the facts of its patent infringement lawsuit against generic drug manufacturer Actavis, stemming from a Paragraph IV certification as to the '504 Patent in the Actavis ANDA

for deferasirox. (The Court will refer to that suit as the "Actavis litigation.") According to Novartis, the clear record of the Actavis litigation demonstrates that any 180-day exclusivity on the 180 mg deferasirox product was obtained and later forfeited by Actavis. Novartis recounts that, on November 20, 2015, it received notice that Actavis had filed Paragraph IV certifications for the '504 Patent for all three strengths of Jadenu. It notes that, at the time, the '209 Patent had not even issued. Moreover, Novartis asserts, the Actavis notice, required by the Hatch-Waxman Act, was the first Novartis received concerning a Paragraph IV certification referencing Jadenu. This information, according to Novartis, leads to the following essential conclusions: that Actavis is "the presumptive first ANDA filer for each Jadenu strength;" that Actavis "likely earned 180-day exclusivity for each strength of Jadenu, including the 180 mg strength," based on its Paragraph IV certification on the '504 Patent; and that Actavis was therefore required to maintain the Paragraph IV certification on the '504 Patent to retain the exclusivity period. (Br. at 15-16.) However, as part of the resolution of the Actavis litigation, Actavis "withdrew the Paragraph IV Certification with respect to the '504 Patent . . . and replaced it with a [Paragraph III] certification . . .." (Id. at 4.) Under the Hatch-Waxman Act, Novartis argues, this withdrawal of the Paragraph IV certification on the only patent which qualified Actavis for the 180-day exclusivity constituted a forfeiture event. It further argues that as the first ANDA filer forfeited the exclusivity, the 180-day exclusivity period no longer exists, and thus there is no basis for Piramal's suit to trigger a forfeiture. In other words, according to Novartis, the Actavis litigation undercuts Piramal's assertions that it has sustained an injury, and thus there is no "case or controversy" to support the Court's subject matter jurisdiction.

The critical flaw with Novartis's argument is that, at best, it creates a factual dispute as to the existence of the 180-day exclusivity period. At bottom, Piramal and Novartis present conflicting evidence concerning when the first substantially complete ANDA for 180 mg deferasirox was filed and, relatedly, whether the first ANDA filer's 180-day exclusivity was forfeited or still exists. Such a dispute is not capable of resolution on the record before the Court, nor would it be appropriate for this Court to turn a Rule 12(b)(1) motion to dismiss filed at this early stage of the litigation into a motion for summary judgment, which would likely fail given the factual dispute.[3]

This case is in the pleading stage; indeed, Novartis has yet to file an Answer. In Lujan, the seminal case on standing, the Supreme Court held that the elements of standing, including injury-in-fact "must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of the litigation." Lujan, 504 U.S. at 561. Elaborating on this holding, the Third Circuit has explained that at the pleading stage, standing is established by "setting forth specific facts that indicate that the party has been injured in fact or that injury is imminent, that the challenged action is causally connected to the actual or imminent injury, and that the injury may be redressed by the cause of action." Anjelino v. New York Times Co., 200 F.3d 73, 88 (3d Cir. 1999). As set forth above, Piramal has proffered ample proofs to support its claim, at this state of

[3] Likewise, the Court will not entertain Piramal's request—improperly raised in its brief in opposition to the instant motion to dismiss—that the Court not only deny Novartis' motion to dismiss but also proceed to enter judgment in Piramal's favor declaring that its ANDA for deferasirox 180 mg tablets does not infringe the '209 Patent. Piramal has provided no basis for converting this motion into a summary judgment motion, and indeed, in is procedurally improper to move for relief under Federal Rule of Civil Procedure 56 in the manner attempted by Piramal.

the litigation, that it has sustained a blocking injury, which, under Caraco and its progeny, is recognized as an injury-in-fact. The evidence proffered by Novartis in an attempt to refute Piramal's assertion of injury does not negate or discredit Piramal's proofs. Far from it. Rather, Novartis' brief is peppered with speculation. For example, it states that Actavis "likely earned" 180-day exclusivity on the 180 mg deferasirox when it filed its Paragraph IV certification on the '504 Patent. It also makes the unsupported assertion that since FDA records reflect that Actavis forfeited exclusivity on the 90 mg and 360 mg products (when it settled the Actavis litigation), "there is no reason to assume that Actavis did not likewise forfeit any 180-day exclusivity period for the 180 mg strength." (Br. at 16.) But, Novartis is in essence urging the Court to make the contrary assumption, that is, that Actavis (or some other company) did, in fact, forfeit exclusivity, in spite of contradictory evidence in FDA sources. Novartis jumps to conclusions and dismisses the FDA databases indicating the existence of a 180-day exclusivity period for the subject drug as "obvious clerical error" (Br. at 16), but this Court sees no reason to reject Piramal's evidence of having sustained injury-in-fact.

While the traceability and redressability elements of Article III standing have not been challenged in the motion to dismiss, the Court addresses them for the sake of completeness. There is no question that Piramal's ANDA for 180 mg deferasirox contains a Paragraph IV certification for a patent listed by Novartis in the Orange Book—the '209 Patent. As alleged by the Amended Complaint, Novartis has thus created an independent barrier to FDA approval of Piramal's ANDA, and the complained-of injury is thus traceable to Novartis. Such a block can only be cleared by a judgment of non-infringement, and therefore, this case meets the redressability requirement for standing.

Novartis has also argued that, even if the 180-day exclusivity period does exist, Piramal has sustained no injury because Piramal's ANDA is unlikely to receive approval until 2021, by which time other competitors with early market entry will have eroded any potential profits Piramal might hope to realize. This argument is unavailing. Whether and when Piramal obtains approval of its ANDA has no bearing on the question of its standing to bring a suit for non-infringement. Daiichi, 781 F.3d at 1364-65 (holding that the Hatch-Waxman Act "makes clear that tentative approval for [the subsequent ANDA filer] is not a precondition to adjudicating the patent issue."). The Federal Circuit, in Daiichi, reviewed the statutory scheme of the Hatch-Waxman Act and concluded that "tentative approval of an ANDA is generally not a precondition to the existence of a case or controversy concerning patents listed in the Orange Book." Id. at 1366. It reasoned that "[w]hen a generic manufacturer seeks to enter the market, the concrete stakes are the market sales upon entry." Id. at 1365. Perhaps seeking to undercut this basis for Piramal's asserted injury, Novartis maintains that there will be no lost market sales when Piramal finally enters the market. Its prediction, however, is completely speculative and unsupported by facts.

In sum, Piramal has met its burden of demonstrating that it has standing to sue Novartis for a declaratory judgment of non-infringement of the '209 Patent. The Court is satisfied that this action presents a justiciable case or controversy within the meaning of Article III. Accordingly, the Court will deny the motion to dismiss for lack of subject matter jurisdiction.

In addition, the Court will deny the alternative request by Novartis to stay this litigation. Novartis takes the position that, in the event the Court finds that it does have subject matter jurisdiction, the Court should stay the litigation so that the FDA may determine whether the 180-

day exclusivity period exists, such that Piramal's ANDA for 180 mg deferasirox is in fact blocked from obtaining final approval. Novartis provides no legal authority for its request, and as Piramal has demonstrated, FDA sources of information indicate that an exclusivity block remains in place for the subject drug. If the parties discover that this fact is false, they should, of course, bring it to the Court's attention. Indeed, it is axiomatic that an actual controversy must exist at the time a complaint is filed as well as through all stages of the litigation for a federal court to have jurisdiction under Article III of the Constitution. Already, LLC v. Nike, Inc., 133 S. Ct. 721, 726 (2013). It is equally well-established that "federal courts have a duty to examine their subject matter jurisdiction at all stages of the litigation." Rose v. City of Allentown, 211 F. App'x 133, 138 (3d Cir. 2007) (citing U.S. Express Lines, Ltd. v. Higgins, 281 F.3d 383, 388-89 (3d Cir. 2002)). Novartis is free to bring another motion to dismiss this case for lack of subject matter jurisdiction based on concrete evidence, if that evidence should come to light. However, based on the current record, the Court sees no reason to delay this litigation.

III. CONCLUSION

For the foregoing reasons, the Court will deny Defendants' motion to dismiss for lack of subject matter jurisdiction, or in the alternative to stay the litigation, in its entirety.

An appropriate Order will be filed.

s/ Stanley R. Chesler
STANLEY R. CHESLER
United States District Judge

Dated: October 16, 2019